UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,701	09/30/2003	Roger Petrus Gerebern Vandecruys	JANS-0063	4563

45511 7590 10/25/2007

WOODCOCK WASHBURN LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, PA 19104-2891

EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
10/25/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@woodcock.com

Office Action Summary	Application No.	Applicant(s)	
	10/674,701	VANDECRUYS ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-28,30,32,33 and 35-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-28,30,32,33 and 35-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/31/07 has been entered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 20-28,30,32-33 and 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures Rickey et al (USPN 5,792,477 hereafter '477) in view of Shimizu et al (USPN 5,824,339 hereafter '339). The claims are drawn to a solid

formulation comprising 9-hydroxy risperidone, or a pharmaceutically acceptable salt, and one or more hydrophilic polymers.

2. The '477 patent teaches a microparticle formulation comprising biodegradable polymers such as poly-lactic acids and 9-hydroxy risperidone, along with other hydrophilic polymers such as polyvinyl pyrrolidone, and carboxymethylcellulose (col. 5, lin. 29-56; col. 13, lin. 60-col. 14, lin. 11). The hydrophilic polymers are present in an amount from 0.5-2% wt. (*Ibid.*). The reference discloses a method for the delivery of the microparticles to a patient (col. 7, lin. 35-43). The reference is silent to the inclusion of pregelatinized starch yet the inclusion of such a common excipient is well known it the art as seen in the '339 patent.

3. The '339 reference discloses antibiotics in combination with various water-soluble polymers (col. 5, lin. 9-35). The hydrophilic polymers include hydroxypropylcellulose with a viscosity between 1-150,000 cps (col. 4, lin. 55-60), and hydroxypropylmethylcellulose with a viscosity between 1-40,000 centistokes (col. 5, lin. 1-8). The formulation can comprise both celluloses at prescribed ratios (col. 6, lin. 52 – 62), in addition to further excipients such as pregelatinized starches and other well-known excipients (col. 6, lin. 42). One of ordinary skill in the art would have been motivated to include the viscous hydroxypropyl cellulose polymers of the '339 reference in order to improve the stability of the microparticle formulation. Further since both reference comprise similar components such as carboxymethylcellulose and other hydrophilic polymers, an artisan of ordinary skill would be able to simply substitute the viscous polymers in order to improve the stability.

4. Regarding the media of changing ionic strength, it is the position of the Examiner that such a limitation is irrelevant to the structure of the tablet formulation and holds no patentable

weight. The structure of the tablet is identical to the combination in the prior art. Further since the fluid is within the gastrointestinal tract, it merely means that the tablet is taken orally, which the combination of the prior art is. For these reasons the limitations are given no patentable weight.

5. With these things in mind it would have been obvious to combine the highly viscous polymers of the '339 patent with the formulation of the '477 patent in order to provide stability and a controlled release to the microparticles. The '447 suggests the inclusion of carboxymethylcellulose, while the '339 patent discloses the use of either carboxymethylcellulose or hydroxypropylcellulose polymers. It would have been obvious to combine the teachings with an expected result of a control releasing formulation of a solid dosage from.

Response to Arguments

6. Applicant's arguments filed 6/29/07 have been fully considered but they are not persuasive. Applicant argues that:

a. The '447 patent does not provide a homogeneous admixture matrix comprising of the instant claims.

7. Regarding this argument is remains the position of the Examiner that despite the amendments the matrix formulations of the '447 combined with the disclosures of the prior art obviate the instant invention. Applicant argues that since microparticles of the '447 patent have a polymer core with a drug coating they are not homogeneous. However the claims indicate that the entire dosage form is homogeneous meaning all of the parts must be the same. If each

microparticle has a drug coating and a polymeric core that any dosage from created from these particles would be the same and the dosage form would be homogeneous. The '339 patent provides a solid dosage from comprising microparticles in an admixture. The dosage form comprises multiple hydrophilic polymers, and pregelatinized starch. The dosage form comprising microparticles comprising a core of polymeric material and a shell comprises a drug. The microparticles are compressed into a solid matrix that is homogeneous. Although the individual microparticles are not homogeneous the overall dosage form comprises the microparticles is homogeneous that the solid matrix tablets. The '447 patent provides a dosage from comprising 9-hydroxyrisperidone and several hydrophilic polymers. The '339 patent comprises the specific viscous polymers of the instant claims and provides a solid compressed homogeneous dosage form. The '339 patent discloses the ratios and concentrations of the instant claims. It would have been obvious to include the active agents of the '447 microparticles into the microparticle formulation of the '339 r include the hydrophilic polymer mixture of the '339 patent into the formulation of the '447 patent in order provide a stable controlled release dosage from. Each patent provides a similar structure and their combination would have been obvious to one of ordinary skill it n the art. For these reasons the claims remain obviated by the combination of the prior art.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER